



Tele: 501/676-2191

Fax: 501/676-3270

# Pool Fisheries, Inc.

1131 Brownsville Loop, Lonoke, Arkansas 72086

**Docket No. 97N-0217****To:**Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr.,  
Rm 1-21, Rockville, MD 20857**From:**Dr. Eric D. Park, Aquaculture Pathologist, Pool Fisheries Inc., 1131 Brownsville Loop, Lonoke,  
AR 72086 (501/676-2191).

1/19/98

**Subject:**Comments on the draft "Proposals to increase the availability of approved animal drugs for minor  
species and minor uses". **Docket No. 97N-0217**

## PROPOSALS

- A. Modification of Extra label provisions.
- B. Removal of Disinfective.
- C. Enhancement of existing programs for data development.
- D. Incentives to pursue minor use drug approvals.
- E. Data sharing by major species NADA holders.
- F. Creation by statute of a "Minor use Animal Drug" program.
- G. Conditional drug approval for minor uses involving non-food animals.
- H. Alternate approval standard/expert review panel for minor uses involving non-food animals.
- I. International harmonization.

The aquaculture industry is, and will continue to be a relatively small and very diverse industry with respect to potential markets for pharmaceuticals. This is especially true for non-food species in aquaculture. Therefore, any step that can be taken to shorten the approval time, cost and especially lower the barriers to drug approval should be seriously considered. Consequently, I found all the proposals to be a good step in the right direction. In my opinion, all of the proposals and their components are important and should be accepted as a package.